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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,720	05/24/2000	Antonio Moroni	498-206	4530

23869 7590 04/23/2003

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/577,790

Applicant(s)

MORONI, ANTONIO

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/3/03 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,8-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuwahara et al. (WO 99/04727). See US 6346119 for translation. Fig. 2 shows a stent-graft with a tubular fabric **13** and a deformable stent **14**. Kuwahara et al. disclose the graft tube is made of a woven fabric having a plurality of fibers, col. 3, lines 1-3. The graft tube is fully capable of being used as a vascular, endovascular or intraluminal prosthesis. Kuwahara also discloses the polyester fibers can be made of polyethylene naphthalate (PEN), col. 4, lines 45-49. With respect to claim 8, the prosthesis can have a coating, col. 4, lines 65-67. Regarding claim 9, the fabric can have about 20-100 filaments, col. 4, lines 59-64. With respect to claim 10, Kuwahara additionally discloses

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the filaments have a denier of 50 and 100 denier for the circumferential drawn yarns or filaments, col. 6, lines 63-66. The examiner asserts that the claimed physical properties (in this case, the material being radiation resistant and hydrolytically stable) are present in the Kuwahara material to some extent even though they are not explicitly recited. All materials can be considered radiation resistant, since they are inherently exposed to some sort of radiation, such as radio waves, visible radiation from lights, etc. or possibly UV radiation. Since there is no objective or quantitative measurements as to ascertain what is considered "radiation resistant" or "hydrolytically stable" the properties are inherently possessed by the prior art material. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art. The fabric is inherently stable at least *about* 120°C because this temperature is well below the melting point of PEN, which is 270°C.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuwahara (WO 99/04727) in view of Vanney et al. (5876436). Kuwahara is explained *supra*. However, Kuwahara does not disclose producing the prosthesis under steam sterilization. Vanney et al. teach that a fabric prosthesis is steam sterilized, col. 8, lines 1-7. It would have been obvious to one of ordinary skill in the art to use steam sterilization on a fabric prosthesis as taught by Vanney et al. with a stent graft of Kuwahara in order to provide a safe, sterile implant for the patient. It is well known in

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the surgical art that prostheses should be sterile for implantation in order to reduce any risk of bacterial infection.

Response to Arguments

Applicant's arguments with respect to claims 1,11,17,18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Rhee et al. (5292802) teach a prosthetic tube that can be made of naphthalene dicarboxylic.

Shalaby et al. (5422068) disclose sterilization methods for devices such as vascular implants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino
April 17, 2003
TC 3700, AU 3738

Brian E. Pellegrino